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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,916	02/19/2002	Steen Klysner	3631-0112P	3837
2292	7590	11/27/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			HISSONG, BRUCE D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,916	<b>Applicant(s)</b> KLYSNER, STEEN	
	<b>Examiner</b> Bruce D. Hissong, Ph.D.	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 77-80, 85-87, 89-94, 100, 133, 142 and 143 is/are pending in the application.
- 4a) Of the above claim(s) 95 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 142 and 143 is/are allowed.
- 6) ☒ Claim(s) 77-80, 85-87, 89-94, 100 and 133 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/2006</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/14/2006 has been entered.

2. Applicant's amendments received on 3/17/2006 cancelled claims 73-75, and Applicant's amendment received on 9/14/2006 added new claims 142 and 143. Therefore, claims 77-80, 85-87, 89-95, 100, 133, and 142-143 are currently pending. Claims 77-80, 85-87, 89-94, 100, 133, and 142-143 are the subject of this office action.

3. The text of those sections of Title 35, U.S.C. not included in this action can be found cited in full, in the previous office action mailed on 12/15/2004.

### **Information Disclosure Statement**

The information disclosure statement received on 3/17/2006 has been considered by the Examiner. The citation for Lee, N, et al as lined through because the publication year and volume number were omitted. A complete citation for this reference appears on PTO form 892.

### **Claim Rejections - 35 USC § 112, first paragraph - enablement**

#### **Rejections withdrawn**

1. Rejection of claim 92 under 35 USC § 112, first paragraph, regarding lack of enablement for a "subsequence", as set forth on pages 6-7 of the prior office action mailed on 9/14/2005, is withdrawn in response to Applicant's deletion of the term from the claim.

Art Unit: 1646

2. Rejection of claims 77-80, 85-87, 89-91, 100, and 133 under 35 USC § 112, first paragraph, regarding lack of enablement for an IL-5 "analog" as set forth on page 7 of the prior office action mailed on 9/14/2005, is withdrawn in response to Applicant's deletion of the term from the claim.

3. Rejection of claims 92-94 under 35 USC § 112, first paragraph, regarding lack of enablement for an IL-5 "analog" as originally set forth on page 7 of the prior office action mailed on 9/14/2005, and maintained in the advisory action mailed on 8/30/2005, is withdrawn in response to Applicant's deletion of the term from the claims.

4. Rejection of claim 85 under 35 USC § 112, first paragraph, regarding lack of enablement for an IL-5 polypeptides comprising specified locations for modifications, as set forth on pages 8-9 of the prior office action mailed on 9/14/2005, is withdrawn in response to Applicant's arguments that the claim specifies particular locations for introduction of foreign T<sub>H</sub> epitopes, and that the specification adequately describes and provides examples of such modifications. However, claim 85 remains rejected for depending from a rejected base claim, as set forth below.

Rejections maintained

5. Claims 77-80, 85-87, 89-94, 100, and 133 remain rejected under 35 USC § 112, first paragraph, regarding lack of enablement for IL-5 polypeptides comprising modifications in any location or position, as set forth on page 8 of the prior office action mailed on 9/14/2005, and subsequently maintained in the advisory action mailed on 8/30/2006.

In the response received on 3/17/2006, the Applicant argues that the claims, specifically claim 85, particularly defines that the foreign T<sub>H</sub> epitope is provided in several defined locations, such as at least one of loops 1-3, or in the amino acid residues C-terminal to helix D, and therefore the specification is enabling for IL-5 polypeptides comprising modification by introduction of foreign T<sub>H</sub> epitopes.

These arguments have been fully considered and are not persuasive. As set forth in the advisory action mailed on 8/30/2006, although claim 85 does limit and specify particular locations for modification by introduction of foreign T<sub>H</sub> epitopes, independent claims 100 and 133 read on IL-5 polypeptides modified at any location within said polypeptide. The

Art Unit: 1646

specification provides guidance and examples showing that foreign T<sub>H</sub> epitopes can be introduced into the IL-5 polypeptides within loops 1-3, and in the amino acid residues C-terminal to helix D. However, the specification is not enabling for any other modifications. One of skill in the art would require further, undue experimentation to make and then use an IL-5 polypeptide comprising a foreign T<sub>H</sub> epitope in any location other than loops 1-3 or the amino acid residues C-terminal to helix D. The skilled artisan would not be able to predict the effects of such modifications on the overall structural/conformation of the resulting IL-5 polypeptide, and would thus not be able to predict whether or not the resulting polypeptide would retain the desired antigenicity when used in methods commensurate in scope with those set forth in the claims of the instant invention. For these reasons, while the specification is enabling for modifications set forth in claim 85, the specification is not enabling for IL-5 polypeptides modified at any other position(s).

**Claim Rejections - 35 USC § 112, first paragraph – written description**

Rejections withdrawn

1. Rejection of claim 92 under 35 USC § 112, first paragraph, regarding lack of written description for a "subsequence", as set forth on pages 3-4 of the prior office action mailed on 9/14/2005, is withdrawn in response to Applicant's deletion of the term from the claim.
2. Rejection of claims 77-80, 85-87, 89-91, 100, and 133 under 35 USC § 112, first paragraph, regarding lack of written description for an IL-5 "analog" as set forth on page 4 of the prior office action mailed on 9/14/2005, is withdrawn in response to Applicant's deletion of the term from the claim.
3. Rejection of claims 92-94 under 35 USC § 112, first paragraph, regarding lack of written description for an IL-5 "analog" as originally set forth on page 4 of the prior office action mailed on 9/14/2005, and maintained in the advisory action mailed on 8/30/2005, is withdrawn in response to Applicant's deletion of the term from the claims.

Art Unit: 1646

4. Rejection of claim 85 under 35 USC § 112, first paragraph, regarding lack of written description for an IL-5 polypeptides comprising specified locations for modifications, as set forth on page 5 of the prior office action mailed on 9/14/2005, is withdrawn in response to Applicant's arguments that the claim specifies particular locations for introduction of foreign T<sub>H</sub> epitopes, and that the specification adequately describes and provides examples of such modifications. However, claim 85 remains rejected for depending from a rejected base claim, as set forth below.

Rejections maintained

5. Claims 77-80, 85-87, 89-94, 100, and 133 remain rejected under 35 USC § 112, first paragraph, regarding lack of written description for IL-5 polypeptides comprising modifications in any location or position, as set forth on pages 4-5 of the prior office action mailed on 9/14/2005, and subsequently maintained in the advisory action mailed on 8/30/2006.

In the response received on 3/17/2006, the Applicant argues that the claims, specifically claim 85, particularly defines that the foreign T<sub>H</sub> epitope is provided in several defined locations, such as at least one of loops 1-3, or in the amino acid residues C-terminal to helix D, and therefore the specification provides adequate written description for IL-5 polypeptides comprising modification by introduction of foreign T<sub>H</sub> epitopes.

These arguments have been fully considered and are not persuasive. As set forth in the advisory action mailed on 8/30/2006, although claim 85 does limit and specify particular locations for modification by introduction of foreign T<sub>H</sub> epitopes, independent claims 100 and 133 read on IL-5 polypeptides modified at any location within said polypeptide. The specification provides examples of IL-5 polypeptides comprising foreign T<sub>H</sub> epitopes introduced into the IL-5 polypeptides within loops 1-3, and in the amino acid residues C-terminal to helix D. However, these examples by themselves are not sufficient to adequately describe the genus of IL-5 polypeptides comprising modification at any position or region. There is no description of any other modification, or a description of any other location within the IL-5 polypeptide that can be modified and still result in an antigenic IL-5 polypeptide. Thus, independent claims 100 and 133 are drawn to a genus of modified IL-5 polypeptides that has not been adequately described in the instant specification.

Art Unit: 1646

**Claim Rejections - 35 USC § 112, second paragraph**

**Rejections withdrawn**

Rejection of claims 92-94 under 35 USC § 112, second paragraph, for lack of antecedent basis for "the IL-5 analog" as set forth in the advisory action mailed on 8/30/2006, is withdrawn in response to Applicant's amendments to the claim to remove the term "analog".

**Claim Rejections - 35 USC § 103**

As set forth in the advisory action mailed on 8/30/2006, all rejections under 35 USC § 103 are withdrawn. In the response received on 3/17/2006, the Applicant argues that there is no motivation to modify the exact regions of the IL-5 polypeptide, as recited in claim 85, in order to practice the instant invention. These arguments have been fully considered and are found persuasive. Additionally, in light of the 35 USC § 112, first paragraph enablement rejection described above, it would not be obvious to modify an IL-5 polypeptide in any position/location by following the teachings of the cited references used in the 35 USC § 103 rejections as set forth in the previous office action of 9/14/2005.

**Double Patenting**

Claims 77-80, 85-87, 89-84, 100, 133, as well as new claims 142-143, remain rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of US Patent No. 6,746,669, for reasons of record set forth on pages 19-20 of the previous office action mailed on 12/15/2004. In the response received on 6/15/2005, the Applicant deferred directly addressing this objection until such time as the language of allowable claims in the instant application is determined.

Art Unit: 1646

**Conclusion**

Claims 77-80, 85-87, 89-94, 100, and 133 are not allowable.

Claims 142-143 are allowable pending submission of a properly filed terminal disclaimer over claims 1-29 of US Patent No. 6,746,669.

This is a request for continued examination of applicant's earlier Application No. 09/980,916. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH  
Art Unit 1646



**ROBERT S. LANDSMAN, PH.D**  
**PRIMARY EXAMINER**